

K983953

JAN 14 2000

510(k) Summary

510(k) Submission Information:

Device Manufacturer: Dade MicroScan Inc.
Contact name: Cynthia Van Duker, Sr. Associate, Regulatory Affairs
Fax: 916-374-3144
Date prepared: December 13, 1999
Product Name: Microdilution Minimum Inhibitory Concentration (MIC) Panels
Trade Name: MicroScan® MICroSTREP *plus*™ Panel
Intended Use: To determine bacterial susceptibility to **Vancomycin**
Indication for Use: For determining antimicrobial susceptibility of aerobic non-enterococcal streptococci including *Streptococcus pneumoniae*
Predicate device: MicroScan® Streptococcus MIC panel (K963641)

510(k) Summary:

MicroScan® MICroSTREP *plus*™ Panels are designed for use in determining quantitative and/or qualitative antimicrobial agent susceptibility of colonies grown on solid media of aerobic nonenterococcal streptococci, including *Streptococcus pneumoniae*

The proposed MicroScan® MICroSTREP *plus*™ Panel demonstrated substantially equivalent performance with streptococcal isolates when compared with an NCCLS frozen Reference Panel, as defined in the FDA DRAFT document "Review Criteria for Assessment of Antimicrobial Susceptibility Devices" (dated May 31, 1991).

The Premarket Notification (510[k]) presents data in support of the new MicroScan® MICroSTREP *plus*™ Panel with **Vancomycin**.

The external evaluation was conducted with fresh and stock Efficacy isolates and stock Challenge strains. The external evaluations were designed to confirm the acceptability of the proposed MICroSTREP *plus*™ Panel by comparing its performance with an NCCLS frozen Reference panel. The MICroSTREP *plus*™ Panel demonstrated acceptable performance with an overall Essential Agreement of 99% for **Vancomycin** when compared with the frozen Reference panel.

Reproducibility testing demonstrated acceptable reproducibility with **Vancomycin**.

Quality Control testing demonstrated acceptable results for **Vancomycin**.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 14 2000

Ms. Cynthia Van Duker
Sr. Associate Regulatory Affairs
Dade Microscan, Inc.
1584 Enterprise Boulevard
West Sacramento, California 95691

Re: K983953
Trade Name: MicroScan® MICroSTREP *plus*™ Panel (Vancomycin)
Regulatory Class: II
Product Code: JWY
Dated: December 13, 1999
Received: December 14, 1999

Dear Ms. Van Duker:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

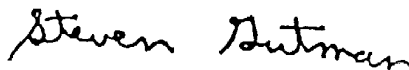
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770)488-7655.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll free number (800) 638-2041 or at (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>"

Sincerely yours,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive, flowing style.

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Page ____ of ____

510(k) Number (if known): K983953

Device Name: MICroSTREP plus™ PANEL - VANCOMYCIN

Indications For Use:

The Indications for Use for the test panel are provided below and in the attachment which follows the FDA recommended format.

The MicroScan® MICroSTREP plus™ Panel is used to determine quantitative and/or qualitative antimicrobial agent susceptibility of colonies grown on solid media of aerobic non-enterococcal streptococci, including *Streptococcus pneumoniae*. After inoculation, panels are incubated for 20 – 24 hours at 35°C +/- 1°C in a non-CO2 incubator, and read visually according to the Package Insert.

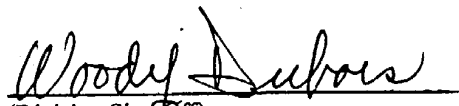
This particular submission is for the addition of the antimicrobial Vancomycin at concentrations of 0.03 – 16 mcg/ml to the test panel

The organisms which may be used for Vancomycin susceptibility testing in this panel are;

Aerobic non-enterococcal streptococci, including *Streptococcus pneumoniae*

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign Off)
Division of Clinical Laboratory Devices
510(k) Number K983953

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ____

(Optional Format 1-2-96)